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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,466	06/20/2001	Arthur L. Herbst	58532-012	9630

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EXAMINER	
FAY, ZOHREH A	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/884,466	ARTHUR HERBST	
	Examiner	Art Unit	
	Zohreh Fay	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-26* is/are pending in the application.

4a) Of the above claim(s) *16 and 18-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-15, 17 and 23-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 13-15, 17 and 23-26 are presented for examination.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13-15, 17 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Collins et al. (U.S. Patent 6,096,728) in view of Kutilek, III et al. (U.S. Patent 5,770,217), Wilder (US 2002/0009421), Bull et al. (US 5,506,145) and Shafran (U.S. Patent 6,297,015).

Collins et al. Teach a composition comprising a COX2 inhibitor such as celecoxib used in the treatment of acute or chronic inflammatory diseases including chronic fatigue syndrome or side effects from radiation therapy. See column 1, line 57, column 2, line 3 and column 32, lines 21-34.

Although, Collins et al. do not specifically teach the fatigue as the specific species of said side effect from radiation therapy, it would have been obvious to a person skilled in the art to use a COX2 inhibitor not only for the treatment of chronic fatigue syndrome but also to fatigue that is a side effect of radiation considering the teachings of Kutilek Wilder, Bull and Shafran.

Kutilek et al. Teach that fatigue is a side effect that is commonly associated with radiation/chemotherapy. See column 16, lines 39-43 and column3, lines 56-63. Bull et al. Teach that that fatigue, fever, chills are signs and symptoms of inflammation,

wherein the treatment of said signs and symptoms can be corrected by treating inflammation. See column 1, lines 32-45.

Wilder et al. and Shafran et al. teach the effectiveness of COX2 inhibitors and its use in the treatment of not only radiation induced inflammation, but also fatigue and other symptoms and signs such as fever and chills as well.

Wilder et al. teach an effective treatment of UV radiation induced photodamage to the skin and symptoms related thereto such as inflammation, weakness, chills, fever, pain and tenderness, using a therapeutically effective amount of COX-2 inhibitors such as celecoxib and refecoxib, see full text, especially pages 28-31 at column 4. The effective dosage regimen for the topical application of COX-2 inhibitor is about 50-400 mg per unit dosage, preferably 100-200mg in suspension or solution, see paragraph 34-45 at column 4.

Shafran et al. Teach a COX2 inhibitor such as celecoxib and its use in the treatment of side effects such as fatigue, fever and chills associated with ifabutin and a macrlolide (e.g. clarithromycin) antibiotic therapy (RMAT) used in treating crohn's disease. See column 5, line 60 thru column 6, line 18. The above reference teaches that symptoms (e.g. fatigue) responded well to COX2 inhibitor such as celecoxib with 200 mg/per day with no adverse effects.

Thus, it would have been obvious to a person skilled in the art to use COX2 inhibitors to treat radiation induced fatigue when these references are combined, considering that the successful result for the treatment of radiation induced fatigue by COX2 inhibitors is readily apparent to any skilled artisan as well as other acute or

chronic fatigues regardless of its pathologies, where reasonable expectation of success would flow naturally from following the suggestion of prior art.

One would have been motivated to combine the teachings of the above references, since they in combination relate to the use of COX2 inhibitors for the treatment of fatigue caused by different reasons. To use a compound being used for the treatment of chronic fatigue and use it for the treatment of fatigue caused by different reasons is considered to be within the skill of the artisan in the absence of evidence to the contrary. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention and as such, claims 13-15, 17 and 23-26 are properly rejected under 35 U.S.C. 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z.F

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600